DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

MD728M

June 21, 1999

WARNING LETTER
CHI-25-99

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Donald H. Breede, President
Hagen's Fish Market
5635 West Montrose Ave.
Chicago, IL 60634

Dear Mr. Breede:

On March 23, 24 and 26, 1999, the Food and Drug Administration (FDA) conducted an inspection of your plant as a follow-up to our previous inspection on June 9, 10, 15 and 16, 1998. At the conclusion of the inspection, you were presented with Form FDA-483, Notice of Observations, Form FD-3501, Domestic Seafood HACCP Report, and FDA 3502, Importer Seafood HACCP Report describing deviations from FDA's seafood processing regulations. The regulations are found in Title 21, Code of Federal Regulations, Part 123 (21 CFR 123), and Good Manufacturing Practice (GMP) regulations for Human Food (21 CFR 110). By virtue of these violations, the seafood products processed at your facility are adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

Specifically, our investigator found the following violations in reference to your hot smoked fish processing:

- Failure to apply appropriate critical limits (Reference 21 CFR Section 123.6(b)). The plan does not address the thickness of fish parts brined and smoked critical to achieving proper water phase salt levels especially since your only data available indicates limited verification of parts representative of thinner fish than others brined/smoked.

- Failure to apply adequate monitoring procedures in the processing of your hot smoked fish (Reference 21 CFR Section 123.6(b). For example, your records for the three-month period (January through March 1999) indicate [redacted] monitoring of chubs only in the drying/smoking process. Chubs are the smallest of what records show is several types of fish in the smoker at the same time. Chubs reportedly are removed from the smoker at the time Vent 1 is closed. The record does not identify this fact. Nor does the record indicate the fish are achieving the minimum [redacted]F [redacted] minutes cook time. There was no further data available to support adequate smoke of the other larger species of fish.

- The Plan is not fish species specific (Reference 21 CFR Section 123.6(b)(2)). You have one plan that covers all fish that are hot smoked. Brine uptake may vary based on factors such as thickness of fish pieces. Several species of fish are smoked at the same time in one oven. The parameters that may vary, such as the critical limits for thickness of pieces, time/temperatures of the cook of each type of variance are not addressed.

- Verification procedures in the plan or implemented are not adequate (Reference 21 CFR Section 123.6(c)(6) and Section 123.8(a)). For example, your plan does not address verification of water phase salt levels in the brine or smoked product and there is no data referenced to insure adequate levels are achieved. Also there is no supporting data that the time/temperatures recorded in the daily smoke monitoring achieve the required levels for the varied fish in one smoke.

You should take prompt action to correct these violations. We are concerned that no substantial improvements or corrections were made since our last inspection in June 1998. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. We are also providing firms the opportunity to take a HACCP refresher course to assist in better understanding and working with the Seafood HACCP program. Please contact the local FDA office for further information. If you enroll in one of these courses, we will consider extending your response or delaying further regulatory action provided products are not critically compromised resulting in an immediate danger to health.

In addition, the following was observed in reference to the HACCP requirements for your operation as an importer of seafood (21 CFR Section 123.12):

- Lack of written importer verification procedures when no Memorandum of Understanding (MOU) exists for the imported product;
- Lack of any affirmative step(s) taken on imported whitefish from Canada; and
- Lack of any product specifications or safety limits for imported seafood.

Your reply relating to these concerns should be directed to the Food and Drug Administration, Attention: Paul Boehmer, Compliance Officer, at the Chicago District Office.

Sincerely,

/s/
Raymond V. Mlecko
District Director